

1 constant of 72.7. But for the others it ranges between 56.8  
2 and 61.5. Okay? There is a clear difference between the  
3 72.7 and the range of ethanol-containing syrups, a clear  
4 difference.

5 The P value on the right-hand side, which is pi,  
6 which is actually a measure of trend. This is a test to see  
7 if a line which compares the effect of the ethanol  
8 concentration to stability is a line that is moving all the  
9 time. So it changes from 2.5, to 5, to 7.5 and 10. It's a  
10 measure of trend. It's not a measure of significance between  
11 the syrup without ethanol and the syrups containing ethanol.  
12 They are clearly different. This information tells you that.  
13 That the trend value, the P value tells you there is no  
14 trend, or no evidence of trend anyway.

15 If you look at 45 degrees we have the same thing in  
16 that the syrup without ethanol has a rate constant of 231 and  
17 that is clearly different for the rate constants for the  
18 ethanol-containing syrups. They range from 173, 10 percent,  
19 to 206 and 2.5. They are clearly different.

20 But in addition, at 45 degrees there is also a  
21 significant trend that as you go from naught to 2.5 to 7.5 to  
22 10 that the stability increases as well.

23 Q After you had made a determination that the UK data and  
24 the U.S. data at 20 degrees was not significant or reliable,  
25 did you report that, your conclusion to Mr. Atkinson?

WALLS REPORTING, INC.  
714 PARK AVENUE, BALTIMORE, MD 21201  
410-728-9020 FAX 410-728-9024

1 A Sorry?

2 Q Did you report that conclusion to Mr. Atkinson?

3 A I agreed to write out a declaration and provide the  
4 information that was necessary.

5 Q Sometime after you decided that the UK data was not  
6 reliable for the reasons you expressed, and the data at 20  
7 degrees centigrade was not reliable for the reasons you  
8 described, did you tell Mr. Atkinson that?

9 A I believe I did, yes.

10 Q And then did there come a time when he requested that  
11 you consider a statistical study at a different temperature?

12 A Yeah, Mike got in contact with me and asked me for more  
13 data. I don't know why he wanted more data. He may have  
14 wanted to have a look at more data closest to room  
15 temperature storage. So I went back to the report and  
16 realized that there was some information that wasn't reported  
17 there but was available, and that it was 37 degrees for the  
18 U.S. ingredients. At that point I asked the statistician to  
19 carry out the analysis at 37, the constant temperature  
20 analysis, and then provide that back to me to add into the  
21 declaration I agreed to write.

22 Q I ask you to look at Plaintiffs' Exhibit 248 in your  
23 binder, that's a memorandum dated October 29, 1990. Did you  
24 send this to Mr. Elahi and ask him to perform a statistical  
25 study on 37 degrees?

WALLS REPORTING, INC.  
714 PARK AVENUE, BALTIMORE, MD 21201  
410-728-9020 FAX 410-728-9024

1 A Yes, indeed. That is what I was referring to there  
2 when Mike wanted a bit more information, and this is my  
3 request to Nadeem Elahi to provide the statistical analysis  
4 on the data and provide the information to me.

5 Q I notice there's a column headed by 37 and it has some  
6 handwritten notations under it. Were they present when you  
7 sent the memorandum to Mr. Elahi?

8 A This version here looks to be the paper copy that I  
9 generated. So I sent an electronic copy requesting it.  
10 There wouldn't have been any information under the 37, that  
11 would have been blank. I would have then printed off a  
12 version of the electronic copy for my records, correspondence  
13 files, and waited for the information to come back.

14 Q If you look at Plaintiffs' 249, is that the memorandum  
15 you received back from the statistical department?

16 A That's right. It didn't come from Nadeem but it came  
17 from Gillian, who was working with Nadeem.

18 Q The numbers listed in that memorandum are the same as  
19 those written in by hand on Plaintiffs' Exhibit 248; is that  
20 right?

21 A Yes, that's correct.

22 Q After those studies were prepared and you received them  
23 back in November of 1990, what did you do?

24 A Well, at that point I drafted the declaration to  
25 support the '249 patent.

WALLS REPORTING, INC.  
714 PARK AVENUE, BALTIMORE, MD 21201  
410-728-9020 FAX 410-728-9024



1 Q If you would look at what has been marked as  
2 Plaintiffs' Exhibit 250, is this the declaration which you  
3 made oath to and signed on April 12, 1991?

4 A Yes, that is.

5 Q Is this a final version of the draft declaration that  
6 you originated in November of 1990?

7 A Yes, it is.

8 Q In paragraph 5 of the declaration you state that in my  
9 laboratory it was found that for an aqueous-based ranitidine  
10 formulation a significant and surprising enhancement in the  
11 stability of ranitidine is achieved by the addition of  
12 ethanol to the formulation.

13 Was that your view then when you made this  
14 declaration and is it your view now?

15 A Yes, it was my view when I made the declaration and it  
16 is my view now. It's a significant enhancement in stability  
17 and the data shows that quite clearly. It's surprising  
18 because it's an invention.

19 Q Now, if you look at the table that you used to support  
20 your opinion on the next page, the table in boxes with  
21 ethanol and without ethanol, was that table derived from the  
22 statistical report that you had received back in May with the  
23 inclusion of the 37-degree data that you received in  
24 November?

25 A That is correct.

WALLS REPORTING, INC.  
714 PARK AVENUE, BALTIMORE, MD 21201  
410-728-9020 FAX 410-728-9024

1 Q That's the source of that information?

2 A That is right. It entirely comes from the original  
3 Nadeem Elahi report plus the 37-degree data that I requested.

4 Q If you will look at the second table, the box on the  
5 final page of your declaration, this again supports your view  
6 that there is a significant and surprising enhancement in the  
7 stability of the product with ethanol; is that right?

8 A Very much so, yes. As I pointed out before, there is a  
9 clear difference between all the ranges of percentages of  
10 ethanol-containing syrup and the syrup without ethanol.

11 Q What was the source of this table, Doctor?

12 A The source of that table again was the Nadeem Elahi  
13 report.

14 Q I believe it's Table 3.1 and 3.2 that you previously  
15 testified about.

16 A Yes, 3.2 in the report.

17 Q Finally, Doctor, there's a fourth program which is  
18 referred to in the introduction on the statistical report  
19 entitled Definitive Experiments, Zantac Solution. Do you see  
20 what I'm referring to?

21 A Yes.

22 Q Would you tell Judge Davis what you found from that  
23 study?

24 A Well, this study is Zantac solution, so it's not the  
25 same formulation as the syrup. This is again comparing

WALLS REPORTING, INC.  
714 PARK AVENUE, BALTIMORE, MD 21201  
410-728-9020 FAX 410-728-9024

1 ethanol and no ethanol programs.

2 This also clearly showed a difference between the  
3 ethanol and no ethanol showing that ethanol provided the  
4 stability enhancing effect and a clearly significant one.

5 Q Is that reflected in the tables, Table 4.1 and 4.2 in  
6 the report?

7 A Yes, it is. Look at table 4.1, which is looking at the  
8 analysis of rate constants for the Zantac solution with and  
9 without ethanol, the ethanol-containing solution has a rate  
10 constant of 217, clearly different from the one, the 262, the  
11 no-ethanol-containing one, and it's highly significant  
12 because the P value is less than .05.

13 Q This information in this data would also support your  
14 opinion that a significant and surprising enhancement in the  
15 stability of the solution is achieved by the addition of  
16 ethanol, would it not?

17 A Very much so, yes, it would.

18 Q And yet from my reading of the declaration, Dr.  
19 Hempenstall, I don't see where you have added this supporting  
20 data; is that right?

21 A That is correct. I felt no need to do so because I  
22 felt that what I put in the declaration was representative,  
23 reliable, conclusive and I didn't feel there was a need to  
24 add that as well.

25 Q A final question. You were in the courtroom on Tuesday

WALLS REPORTING, INC.  
714 PARK AVENUE, BALTIMORE, MD 21201  
410-728-9020 FAX 410-728-9024



1 and the U.S. ingredient syrup, that is just generically,  
2 comparing those two. I don't know about these batches here.  
3 I don't know about the batches that were set up. I have  
4 explained when you look at the two of them as described in  
5 the documents they have a slightly different way of  
6 expressing ethanol, but other than that they are the same.

7 Q What is the different way of expressing ethanol?

8 A It's calculated in a different way. I can't remember  
9 the exact details now. It's to do with the specification of  
10 ethanol in the USP against the ethanol in the BP.

11 Q That is for testing for identity purposes, correct?

12 A I would have to refer to it. I can't recall.

13 Q Did you use the same amount of ethanol in -- I'm still  
14 on Defendants' 16, did you use the same amount of ethanol in  
15 all the programs under number one as you did under number 2?

16 THE COURT: I'm sorry, Mr. Rubin; he said  
17 repeatedly he didn't do the testing. He didn't do the  
18 testing so he didn't use any alcohol or ethanol; am I right?

19 THE WITNESS: That's right, I didn't do it. I  
20 didn't set them up.

21 THE COURT: His testimony on direct I thought was  
22 very clear. He compiled some statistics and he got a report  
23 and on the basis of his analysis of that report he did a  
24 declaration. That's what he did.

25 MR. RUBIN: Your Honor, there was testimony during

WALLS REPORTING, INC.  
714 PARK AVENUE, BALTIMORE, MD 21201  
410-728-9020 FAX 410-728-9024